

REMARKS

The pending claims 1-17 and 21-30 have been rejected. Claim 6 has been amended. Reconsideration of the present application, as amended, is respectfully requested in view of the following comments.

Claim 6 was rejected under 35 USC §112, second paragraph, as being indefinite for lacking antecedent basis for "the ratio." Claim 6 has been amended to change this term to read -- a ratio--. This correction is believed to address concerns raised under §112, with no change to the claimed scope or substance being made thereby.

Claims 1, 7, 8, 21-23, 26, 27, 29, and 30 were rejected as being anticipated by U.S. Patent 5,354,305 to Lewis, Jr. et al. (the Lewis reference). The applicant respectfully traverses. In order to establish anticipation, each and every element and limitation of the subject claim must be disclosed in a single reference. Furthermore, for an element to be inherent to a given reference, it must "necessarily be present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson, 49 U.S.P.Q. 2d 1949, 1950-51 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991)). Indeed, inherency "may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." 49 U.S.P.Q. 2d at 1951. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." Ex parte

Levy, 17 U.S.P.Q. 2d 1461, 464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original).

It should be appreciated that the Lewis reference is singularly focused on the application of a repair device for nerves. In contrast, the present application is directed to fractures of long bones. Nerve tissue and bone tissue differ in a number of respects. For instance, “when reconnection of the nerves is attempted, a tensile force may be created in the severance as they are drawn together, complicating both the process of rejoining the severed ends, and the healing process.” (See Lewis, column 1, lines 27-32). According to the Lewis reference, nerve issues are generally provided in fascicle bundles. (See Lewis, column 5, lines 40-46). Furthermore, nerve tissue is generally soft and subject to displacement as compared to the relatively rigid and hard outer portion of a bone. In contrast to the tensile forces to which severed nerve tissue is generally exposed, a long bone, such as the femur, “is a major load-supporting bone which, in use, is subjected to substantial axially-directed compressive loading and is subjected to frequent and substantial torsional loading.” (see U.S. Patent 4,862,883 to Freeland (the Freeland reference), column 1, lines 60-63). Thus, the devices and processes directed to treatment of severed nerve tissue are expected to vary significantly from that directed to fractured bone.

Indeed, the Lewis reference fails to disclose expressly or inherently several features of the invention defined by claim 1. For example, there is no express or inherent teaching of proximal and distal end sections that provide rigid anchoring locations relative to a central section where such central section provides flexibility to promote healing of a fracture. In fact, such flexibility would seem to be inapposite to the healing process desired for nerves because with flexation of a nerve repair device, the severed nerve pieces would likely separate due to the

tensile forces that tend to pull the nerve pieces apart. Thus, it is respectfully submitted that the Lewis reference fails to disclose various features of the invention defined in claim 1.

Beside the patentability of claim 1, further reason support patentability of claims depending from claim 1. For example, the features of the dependent claim 21 include one of the fastener receiving areas in the distal end section having at least two holes extending transverse to the longitudinal axis each being normal to the longitudinal axis and one another (emphasis added). Thus, in addition to the proximal end section with at least one hole, there is a distal end section with at least two holes -- making a total of at least three holes in the device. Such features are not expressly or inherently disclosed in the Lewis reference.

In another example, dependent claim 22 recites that the nail is made from titanium and has a solid central section of between about 4 millimeters and 7 millimeters. First, the Lewis reference fails to disclose or teach composition from titanium. Also, even though it was admitted in the Office Action that Lewis discloses in column 4, lines 18-24 a width of about 0.05 inches (approximately 1.27 millimeters) or smaller to allow implant 12 be more easily inserted longitudinally between the fascicle bundles (emphasis added), the incongruent argument is apparently made that the Lewis device is inherently capable of such features. In order to be inherent, the feature must necessarily flow from the teachings of the reference (emphasis added). Such is not the case here -- especially given the preference for an entirely different range of 1.27 millimeters or less. Accordingly, the dimensional feature of 4-7 millimeters recited in claim 22 is not disclosed by the Lewis reference. Accordingly, further reasons support patentability of the rejected claims depending from claim 1.

Among the features of independent claim 26 are fastener receiving areas each having a solid cross-sectional dimension greater than a solid cross-sectional dimension of the central section. The Lewis reference is silent as to whether it is solid or hollow, including tip portions 14, 21, and the like. Moreover, because such portions of the Lewis device could be hollow, such cross-sectional dimensions as defined by claim 26 are not inherent in the Lewis reference. Accordingly, the Lewis reference also fails to anticipate independent claim 26.

Additional reasons support the patentability of claims depending from claim 26, that were also rejected as being anticipated by the Lewis reference. For example, claim 27 recites that at least one of the fastener receiving areas includes two holes axially oriented normal to one another and the longitudinal axis. Accordingly, the fastener receiving areas of claim 27 include at least three holes. Moreover, two holes in one of those areas are normal to one another and the longitudinal axis. None of these features are disclosed either inherently or explicitly by the Lewis reference. In a further example, claim 29 recites the nail is made titanium and has a diameter of the cross-section of between about 4 and 7 millimeters. The Lewis reference is silent as to the composition including titanium and fails to inherently or explicitly disclose a diameter with a dimensional range defined by claim 29. Thus, further reason support the patentability of claims depending from claim 26 that were rejected on like grounds.

Claim 6 was rejected as being unpatentable over the Lewis reference stating that "since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." The applicants respectfully traverse. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." Manual of Patent Examining Procedure (MPEP) §2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Moreover, the suggestion/motivation to combine or modify under §103 needs to be specific. Where a "statement is of a type that gives only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it ... [s]uch a suggestion may make an approach 'obvious to try' but it does not make the invention obvious." *Ex parte Obukowicz*, 27 U.S.P.Q. 2d 1063, 1065 (U.S. Pat. and Trademark Off. Bd. of Pat. App. & Interferences 1993) (citations omitted).

The general assertion that features of claim 6 involve discovery of optimum or workable ranges is akin to an "obvious to try" rejection which has long been held to be improper. Moreover, the ratio recited in claim 6 does offer certain key advantages in the treatment of children with the device claimed thereby. Problems regarding the healing of the long bones, particularly for a child, are described by way of example in the Background of Invention section of the present application and the surprising discovery of a nail with features to address these problems is described, for instance, on page 11, line 9-page 12, line 12 of the present application. Accordingly, additional evidence supports the patentability of the specified ratio of claim 6. See, In re Chu, 36 U.S.P.Q. 2d 1089, 1094 (Fed. Cir. 1995) (stating that "the Board was not free to disregard the evidence and arguments presented by Chu [patentee] in response to the obviousness rejection" based on design choice). Moreover, the teachings of the Lewis reference

comprise nonanalogous art that is inappropriate to assert under §103 given the contrasting nature of severed nerve tissue versus fractured bone. Accordingly, the rejection under §103 should be withdrawn.

Claims 2-5, 9, 16, 17, and 28 were rejected under 35 USC §103 as being unpatentable over the Lewis reference in view of the Freeland reference. The applicant respectfully traverses. “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” In re Fritch, 23 U.S.P.Q. 2d, 1783-84 (Fed. Cir. 1992) (holding that a combination of references does not render a claim obvious due to a lack of suggestion or motivation to combine or modify). As a corollary, the patent office has recognized that “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” Manual of Patent Examining Procedure (MPEP) §2143.01. MPEP §2143.01 also states that “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” Likewise, there must be some reasonable expectation of success with regard to the asserted combination (MPEP §2143.02).

In this portion of the Office Action, it is admitted that the Lewis reference fails to teach a bending device. Instead, the Office Action turns to the Freeland device to teach such features, specifically referencing Figs. 19-21 of Freeland. As a careful review of Figs. 19-21 and the accompanying text of the Freeland reference will reveal, it fails to disclose any type of bending device. Instead it merely describes a tool to prevent downward displacement of the rod R. (See

Freeland, column 12, line 66-column 13, line 19, for example). Moreover, commensurate with its nonanalogous nature, it is respectfully submitted that modifying the primary reference (the Lewis reference), directed solely to the repair of nerve tissue with a secondary reference directed to bone repair (the Freeland reference) is improper because the vast differences in the tissue types involved would not suggest the desirability of the combination or otherwise motivate it. In fact, bending and curving the Lewis device would appear to render it unsatisfactory for its intended purpose because the resident tensile forces would tend to pull the nerve ends apart rather than joining them together.

Turning to independent claim 16, it is respectfully submitted that in addition to the absence of a bending device, any attempt to actually bend the hollow tubular rod R of the Freeland device before or during insertion in the bone would interfere with, if not destroy, the ability to deploy blades B of the Freeland device from the undeployed state shown in Fig. 2 to the deployed state shown in Fig. 1. (See column 7, line 59-column 8, line 19 of the Freeland reference). Indeed, if tubular rod R or insertion tool I situated inside rod R are bent or curved before insertion in the bone, the Freeland device would likely be rendered inoperable. Accordingly, it is respectfully submitted that several reasons support the impropriety of the rejection of claim 16.

Besides patentability of the respective base claims, further reasons support patentability of dependent claims rejected with the Lewis/Freeland combination. For example, as to dependent claim 3, none of the references teach or suggest that the central section be curved in the matter cited therein. Likewise, the more specific bends and features recited in dependent

claims 4, 5, and 28 are not in either reference -- and in fact are discouraged by these references given the negative results from bending of the Lewis or Freeland devices.

Among the features of the dependent claim 9 are cross fasteners respectively received in the holes that have the threaded distal tip adapted to engage bone matter. Such a threaded fastener would do extensive damage to nerve tissue if utilized in conjunction with the Lewis device in place of one of its piercing pins, which further undermines the intended use of Lewis. As a result, further grounds indicate the required suggestion or motivation to combine is absent. Thus, numerous reasons support the patentability of the rejected dependent claims based on the Lewis/Freeland combination asserted.

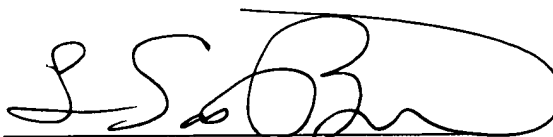
Claims 10-15, 24, and 25 were rejected under 35 USC §103 as being unpatentable over the Freeland reference in view of the Lewis reference. The applicants respectfully traverse. As an initial matter, although the roles of the primary and secondary reference are reversed in this rejection, the inconsistencies that result from using one to modify the other due to the vastly different tissue types, also fails to provide the requisite suggestion or motivation to combine the references in the matter asserted. Moreover, there are several misunderstandings as to what the references teach in regard to this rejection. For example, the Freeland device clearly includes a hollow tubular rod R in which different tools such as tool I or tool T are inserted. Likewise, there is no indication expressly or explicitly in the Lewis reference that its cross section is solid instead of being hollow. Indeed, to modify the Freeland device to include multiple fastener receiving areas at opposite end portions would unduly complicate the device, discouraging one skilled in the art from practicing such modifications or having a reasonable expectation of success therefrom. Moreover, it would likely interfere with the relatively complex mechanical

operations involved in properly deploying blades B of the Freeland device. Thus, it is respectfully submitted that the rejection of claim 10 is also improper.

Additional reasons support the patentability of rejected dependent claims based on the Freeland/Lewis combination, as asserted. For example, dependent claims 11-15 include various unique, innovative curve and bending features that are not taught or suggested by either reference. In another example, dependent claim 24 recites that another hole extends normal to the longitudinal axis of the elongate member -- again totaling three holes or more in the device. Such features are also not taught or suggested by either reference individually or collectively.

In view of the foregoing, it is believed that claims 1-17 and 21-30 are in condition for allowance. Reconsideration of the present application as amended is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone or respond to any outstanding matters concerning the present application.

Respectfully submitted,

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